In the Matter Of:

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY

DEPOSITION OF

LLOYD R. SABERSKI, M.D.

January 12, 2017

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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	**MDL NO. 02419**
	DOCKET NO. 1:13-MD-2419-RWZ

THIS DOCUMENT RELATES TO:

All Actions

Deposition of LLOYD R. SABERSKI, M.D.

Baltimore, Maryland

Thursday, January 12, 2017

10:00 a.m.

Reported by: Angela McKinney, Court Reporter

Deposition of LLOYD R. SABERSKI, M.D., held at the offices of:

LAW OFFICES OF PETER G. ANGELOS
One Charles Center
100 North Charles Street
Baltimore, Maryland 21201
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Pursuant to agreement, before Angela McKinney, Professional Court Reporter and Notary Public of the state of Maryland.

dispute that?

MR. COREN: Objection to form.

A Well, that's their customer list. It's not apropos to this case. NECC had many customers. The issues here are steroids. I think there's only 76 providers that got compounded steroids.

BY MR. KIRBY:

Q Well, as a matter of fact, it wasn't just MPA that was recalled by the government, right, NECC's MPA? It was other drugs that NECC produced, right?

A Correct.

Q And part of your opinions involve the standard of care of purchasing medications from a compounding pharmacy, right?

A That is correct.

Q And you have to utilize a particular amount of due diligence or order in a particular way, right?

A Yes.

Q So that's not just for the purchase of MPA?

A That's using a compounding pharmacy.

Q You practice in Connecticut. Other than those states that you listed that you do expert work

A Yes. I wrote it down this morning just so that I'd get it right. The Federal Food, Drug and Cosmetic Act of 1938.

Q Anything else?

A Well, over the years that law evolved and had a number of different codifiers. It was adjusted over the years, but that was the principal law that was put into place.

Q When did you look up the Federal Food, Drug and Cosmetic Act of 1938?

A A couple years ago.

Q Do you know specifically what you would say they violated with regards to that Federal Food, Drug and Cosmetic Act?

A Almost everything involving compliance.

Q Can we agree that NECC's conduct in these cases caused injury to the patients?

A Well, I think their conduct in conjunction with the misconduct of the physicians caused injury to patients.

Q Fair enough. At least in part we can agree --

after being alerted to this, and the risks are just the same with any compounding pharmacy.

Q I know that in medicine a lot of times doctors want to be certain about things and they want to be as concrete as they can. With regards to your expert testimony, it's just more likely than not is the standard in terms of your opinion. Are you able to say more likely than not or would you say more likely than not that the patients that we're dealing with here, these eight, would have received contaminated steroids if NECC had been stopped from selling before May 2012?

MR. COREN: Objection to form.

A I think there's another way to clarify it. There are absolutes here. I mean there is always the possibility that getting your compounded substance from a compounding pharmacy, there are higher risks than getting it from a manufacturer. But the probability here is if you stopped NECC from delivering its product, you would reduce the risk.

BY MR. KIRBY:

Q Right. But reducing the risk -- and we'll get to that in a little bit. You are not saying more

likely than not they still would have received contaminated product?

A The risk is always higher with compounded steroids. Always. If you are getting a compounded steroid from a compounding pharmacy, the risk of infection or adverse event is much higher and therefore you should never do that because, first of all, there is no benefit whatsoever that I can think of that you can get from a compounding pharmacy. All you get is risk. So there is never, ever a reason to order a product from a compounding pharmacist or a compounded product from a compounding pharmacist.

Q I understand you keep saying there is increased risk, and we'll talk about that later. But to answer my question, are you going to say more likely than not these patients still would have gotten contaminated steroids if NECC had been stopped from selling the MPA at issue prior to May 2012?

MR. COREN: Objection to form.

A They certainly wouldn't have got NECC's contaminated steroids. They would have probably, based on Dr. Bhambhani's testimony, they would have gotten a

compounded steroid from another compounding pharmacy of which all compounded steroids from compounding pharmacies have a higher risk of adverse event than a manufacturer.

Q So I'm not -- I don't know if we're on the same page here. All I'm asking is would they have still received contaminated steroids more likely than that? I understand you are talking about risk, but are you here to say that even if NECC had been stopped from selling MPA before May 2012 that they still would have gotten contaminated steroids and had the same injury?

A No, they wouldn't have had the same injury, but I just made the point that if you look at the history between 2000 and 2012, there are whole lot of issues with compounding pharmacies. Not just NECC. So compounding pharmacies in general have had a lot of problems delivering end product. So to answer your question here, and I'm not trying to be evasive -- I mean, look, if they didn't get the NECC product, they probably wouldn't have gotten the fungal infection. But if she continued with a compounding pharmacy, there is a higher risk of having an adverse problem. It's

not going to be the problem they had with NECC.

Q I'm just talking about these patients.

A Well, yeah, it's a small -- it's an increased risk using a compounding pharmacist.

Q Other than what you gave me that was in your folder, you showed me what's in your folder, and what's listed in your report, have you reviewed anything else? And maybe the Federal Food, Drug and Cosmetic Act of 1973, but anything other than that?

A Yeah, I've shared everything.

MR. KIRBY: Let's take a quick break.

(Recess)

BY MR. KIRBY:

Q Doctor, we were talking earlier about your expert work. Would you consider this a medical malpractice case or some other type of case?

A Malpractice.

Q Sterile injected corticosteroids that are used for epidural injections are not something that patients could administer themselves, right?

A No.

Q You'd consider it requires a skilled

this case. And I trust that you are here to opine that Dr. Bhambhani breached standards of care, correct?

A Yes.

Q So why don't you give me that list and then we can get into more detail and go through each one separately.

A If you turn to page four of my written opinion, I think that outlines it fairly concisely, 1 through 9.

Q Okay. Failing to exercise reasonable care -- I'm just going to read it. Failing to exercise reasonable and prudent care to ensure that the steroid preparations used for injections were sterile, free of contaminants and compounded in accordance with all applicable industry standards, correct? Did I read that right?

A Yes.

Q So explain that to me. What do you mean by that and what are the bases for your opinions in that regard?

A The only way this can -- the best way to ensure the safety of the medications you use for

injection on your patients is to get an FDA-approved product from a manufacturer. She did not.

Q And why do you say that?

A Because she did not.

Q What's the basis for saying that the only way you can get a safe product is by going to an FDA manufacturer?

A Well, we have data. It turns out that if you look at the history of infections pertaining to -- any sort of a number of infections pertaining to steroids, I think over the past 50 years there is quite a number of infections that have occurred. I think 100 percent of those infections have been from compounded pharmacies and zero from manufacturers. There has not been a single manufacturer in the United States who has ever had an infection related to steroids.

Q Do you have any literature or anything to back that up, to support that?

A It's well published.

Q What I mean is can you cite to me any articles or anything that I could find?

A No, but it is well published. You will find

that there is not a single infection from manufactured steroids causing epidural infections. In fact, in the last tally of the last 12 years, let's say the 12 years before 2012, I think there are 12 cases of infection that have been recorded and there is zero from the manufacturers. So very compelling overwhelming numbers.

Q Would you agree that a fungal infection in general is a very rare occurrence?

A Yes.

Q When you say -- well, number one, you don't expect or you wouldn't expect a health care provider to actually test the drugs that they get, would you?

A No. But I would expect them to do what's customary and expected when they use a parenteral injection to make sure they are using a product that has a higher probability of being safe.

Q So like what?

A A manufactured product from an FDA approved manufacturer.

Q Okay. So there is nothing that they could do -- are you just saying you can't purchase from a

compounding pharmacist?

A You can only purchase from a compounding pharmacist if there is actually a need for the compound. So if the person has a special need -- as you pointed out, they had red hair or they are obese and they have some special need that an FDA product does not provide, sure, they can use a compounding pharmacist as long as they communicate with the compounding pharmacist in an appropriate standard which is a prescription that lays out all the things that are special about your patient.

Q So I've lost you. How would that situation ensure that they were getting a safe product from that compounder?

A You would only use the compounder on an occasional basis when the need arises. Compounding agencies are not designed to be a substitute for manufacturers. They are only available to provide for those patients, and it's been estimated between 1 and 3 percent of the patients that need special compounding. Compounders are not available to provide stock. If you use a compounder for stock, you are going to run into

problems because the probability of having a problem with their processes is much higher and a greater risk than that of a manufacturer.

Q So what if a physician typically used a particular drug, and let's just say they typically do the same procedure over and over -- and I'm not relating it to this case -- but that drug wasn't available from an FDA-registered manufacturer. Wouldn't they be using that compounder over and over and over again? It wouldn't be very rarely?

A They would have to write a prescription for that patient specific with that patient's need to get that compounded product to be in accordance to the law.

Q But we can agree that that wouldn't make that drug that they got from the compounder any safer, would it?

A No, but it would decrease the risk to other patients. You would only get it when necessary.

Q So what if a physician continually used a compounder, and let's say they did it for every patient that had a specific need and they sent in a patient-specific individualized prescription all the

time, that's what they did, and got their drugs from a compounder. That wouldn't change the safety issue, would it?

A No. In fact, the safety issue would be exactly the same. Compounding pharmacies are at higher risk of having infection than manufacturers. So that is a given. The literature is rock solid on that. There is absolutely no benefit in going with a manufacturer for your general patients -- excuse me, no benefit in going with a compounder for general patients. All you add is risk, the risk of infection. Obviously a manufacturer does not have those risks. Certainly the risk is there, but the probability of having a problem with a manufacturer is far less than with a compounder.

Q You have cited 12 cases I think you said in which compounders have had infection events, correct?

A Correct.

Q Out of how many? Out of how many units? That's 12 out of how many? What percentage of drugs would that be?

MR. MILLER: If you know.

A It would be a much higher risk than using a manufacturer.

Q I get that, but that's not very helpful.

A It's very helpful because when it comes to decision making, it's not an issue of numbers. It's an issue of putting your patient at risk. Every decision a doctor makes is putting the patient at less risk. Even if the difference was rather small, you are always going to choose that which provides the patient less risk.

Here's a case where compounders provide zero benefit. There is not a single shred of evidence anywhere ever published that shows that compounding provides any benefit, but there is an awful lot of data out there that shows that it provides risk.

Q But you can't give us the percentage?

A Nobody can give you the numbers because nobody has really collected the numbers.

Q Is it less than 1 percent? When you say an increased risk, I don't know if you are talking 50 percent risk or 25 percent risk or what.

MR. COREN: Objection to form.

use, you consider the risk to the patient and I guess the percentage risk. But when you are considering the risk -- hold on. Let me finish. If it's a difference of .02 percent risk versus .3 percent risk or something, it's an increased -- it might be an increased risk, but it's insignificant, isn't it? Don't you have to consider that?

A No. You are making a mistake here. Before you consider the risk benefit profile or the risk profile, you have to see is there benefit.

Q So you have to know the numbers, don't you?

A Before you get there, you have to decide if I'm going to use this product, is there a benefit. Once you have established that there is a benefit, then you can start conjugating on the numbers. But here in this case, there is no benefit. There has never been a benefit. There is no reason to use this product. So nobody who is rationally thinking of this can find an arguable reason to offer the product.

Now, if there is a reason for doing it, let's say the patient has some weird allergy or some weird intolerance or something weird and they go to the

compounding pharmacist, they can make something up that's appropriate for that patient. At that point, we can talk about the appropriateness of the risk. But you can never manufacture products at a compounding pharmacy. If you start manufacturing it -- first of all, it's against the law. They can't do that.

Q So you are saying that there is absolutely no benefit to compounding pharmacies; it's just an increased risk?

A For injectable deposit steroids, yes.

Q And you read Dr. Bhambhani's deposition, right?

A I have.

Q Okay. And you read that she believed there was a benefit in this case to using the drugs from NECC, right?

A Not only was she wrong, she was wrong by more than a decade.

Q Well, let me step back. You saw her discussion, I hope, about using her experience using triamcinolone and betamethasone. Do you recall that?

A Oh, I do, very much so. She is confused

because the problem she associated with triamcinolone and betamethasone have nothing to do with preservatives; had everything to do with the mineralocorticoid and glucocorticoid activities of the drugs they inject. It had nothing to do with preservatives, so her argument made no sense scientifically.

Yes, she had a concern. She had some problems with betamethasone and triamcinolone. She was open to using a different product. It was mentioned to her by one of her colleagues. She went ahead and ordered it. No due diligence.

Q And in her mind, there was a benefit and a different therapeutic effect by using NECC's drugs compared to betamethasone and triamcinolone, right?

A Well, I don't recall that. But even if there was, it's not substantiated in the literature. All three products, Depo-Medrol, triamcinolone and betamethasone, the outcomes are thought to be clinically the same.

Q Would you agree that there was some contingent of respected pain physicians who believed

wanted it out. It doesn't make any sense.

Q How is the benzyl alcohol protecting the patient?

A Well, it makes sure if you are using a multidose vial that you do not introduce -- if you introduce bugs, they are less likely to grow and proliferate.

Q So that's right. So that's not for purposes of -- that would do nothing with -- it's not for contamination that's introduced in the manufacturing process, right?

A No. When the manufacturing process is so far afield from being proper, the amount of bacteriostasis that you have probably wouldn't overwhelm it.

Q So what is the added benefit of the benzyl alcohol in this case?

A Well, benzyl alcohol has to be placed in multidose vials. There is no such thing as a multidose vial without benzyl alcohol. It's a deviation from acceptable medical practice to have a bottle with 5 milliliters of fluid and to stick a needle into it five

separate times to extract fluid five separate times to distribute to five patients. That is an egregious deviation from how we practice aseptic technique.

Now, if you want to do that technique, you know, use a multidose vial, the product has to have benzyl alcohol or some equivalent of benzyl alcohol in there to cause bacteriostasis.

So in this case we have methylparaben -- methylprednisolone that's benzyl alcohol-free in multidose vials without benzyl alcohol. And the problem here is that by entering the needle multiple times, she is actually -- by using that same bottle for multiple different patients, she is actually potentially introducing that infection to multiple patients.

Q You are not suggesting that that was the case here, are you?

A Yes.

Q So then what's your opinion in that regard?

A Well, there is a high probability that, I can't say for sure, but on August 21, two patients who are involved in this case here got injections on the

same day. And we know from Dr. Bhambhani's testimony that she uses the bottle over and over again until it's empty. And at the end of the day, if there is any left over, they throw those bottles out. So there is a reasonable degree of possibility that Torbeck and Rozek on August 31 got injections from the same bottle.

Now, the issue here is if she was using single dose -- if she wanted to have something that had less benzyl alcohol, there are single-dose vials. And if she used a single-dose vial, she would not have had this situation of introducing potentially infection from one bottle to multiple people.

Q So tell me exactly your understanding of Dr. Bhambhani's technique when she is doing epidural steroid injections, and in this case with regards to multiple patients.

A Well, the issue pertains to the steroids. She has 5 milliliter bottles of methylprednisolone benzyl alcohol-free. There is no such -- that is an oxymoron. There is no such thing as a multidose benzyl alcohol-free bottle. So what she did is she used -- I should take that back. I suppose if she used all 5

cc's for one patient, that could be a potential legitimate use, but there is no possibility -- generally in clinical practice, we don't use that much for one patient. She said in her deposition she will enter those bottles three to five times to withdraw medication for her patients.

Q With different syringes each time?

A Irrelevant. Irrelevant.

Q Are you aware of any literature that allows for the safe use of a multidose vial in a way that Dr. Bhambhani did?

A It's not supposed to be done that way.

Q Says you?

A Aseptic technique. Let me be very clear here. The only thing that made it a multidose vial is it had a stopper. The preparation was not the appropriate preparation for a multidose vial. Aseptic technique: When you are using this product that was not designed as a product to have repetitive needles inserted, it can only be used once.

Q So if there is literature out there that supports the technique in the way that Dr. Bhambhani

acted in this case with regards to using that vial multiple times, you would disagree with that?

A Well, I don't believe there is any literature. I have specifically looked at that and basically what the literature says in circumstances where you are stuck in the situation, you have to take an extra amount of time to safely prepare the materials. So the point is you are not supposed to be in this situation. I mean, if the situation develops, then there are steps that you can take to ameliorate or minimize your risk, but obviously you never want to be introducing a needle into a vial multiple times that has no way of protecting the solution. Obviously the concern here is if they are using a contaminated bottle, that contamination could be spread to multiple people.

Q So it's your position that no other reasonably prudent physician would act in the way that Dr. Bhambhani did with regards to using the multidose vial that way?

A Yes.

Q And if it was in literature, then that would

be completely incorrect?

MR. MILLER: Objection. Asked and answered.

A Well, it's not in the literature. As I said, there is a caveat here that you can prepare it in special circumstances. But when you have a multidose vial, it has to have some kind of bacteriostatic substance in there to protect the patient.

BY MR. KIRBY:

Q I know you said a second ago that you think it's possible that Dr. Bhambhani introduced the contamination. You are not saying that she introduced fungal contamination into the vial, are you?

A No, but I'm saying that she vectored it from the vial to two different patients. And if the vial was thrown out after use -- when you have a vial that does not have preservative in it, after you use it you are supposed to throw it out. But she didn't do that. She used it for the next patient. My whole point here is these vials were contaminated sort of like a Russian roulette; some were badly contaminated and others weren't. So she happened to have had a bad vial. Unfortunately, because of her practices, she was able

to spread that bad vial with all its badness to other people, and potentially five people if she used it five times. If she stuck to the standard of care, she would have thrown that vial out and there would not have been four other opportunities for people to get that bad drug.

Q So how can you say -- do you have any evidence to show me that if she had thrown the bottle out then the next bottle she used that's part of that recalled lot wouldn't also have contaminated steroid?

A Well, you're right, I don't have that, but we know that not every single bottle was contaminated. It was Russian roulette. And there is a reason for that. Because in compounding, which differs from manufacturing, the steps are done by hand. Whenever you do things by hand, there is more of a chance of having error. That's why compounding has a higher risk of having problems like infection. So in all likelihood, some of the vials got compounded in a way that was much more deleterious than others.

Q You can't say, though, that if let's say two vials were used on August 31, for example, that the

that diminished over time. And as I said, the literature strongly supported no risk by the late '90s.

Q And based on her testimony, she had a good-faith belief that using the MPA from NECC was reducing the risk to her patients; do you remember seeing that?

MR. COREN: Objection to form.

A And obviously she was wrong and naive because the very product she was using increased the risk. How could she possibly think that a multidose vial with no preservative was safer? I mean, that's inconsistent with everything we teach with aseptic technique.

BY MR. KIRBY:

Q Other than the eight years that she used it with no incident?

A Hey, there is a standard of practice here. Just because she got away with it doesn't mean she was okay. It's always wrong and you are not going to get a physician in here to say that that was appropriate.

Q Well, she wouldn't have been the only one who, quote, got away with it, would you?

steroids, manufactured steroids, cause a problem. Zero. That was a discussion at one time, but that is no longer the case.

Q But that's as of the late '90s, it's debunked?

A Yes.

Q So you wouldn't believe that -- that wasn't common in a portion of your field within pain medicine in 2012?

A Definitely not. If somebody was talking about it and had some opinion about it, it was certainly in the minority because there is a vast copious reservoir of literature that says they are wrong. In fact, almost every society that involves themselves with epidural injections like ASIPP that you mentioned has no documentation that there is a risk with these injections in the epidural space with manufactured product.

Q So let's just be clear because initially I think you said it's absolutely debunked or absolutely no one would think that or absolutely if anyone did, they'd all be wrong and then you just said there might

be a minority of people. So can we agree that there may be some, whether it's a minority or 50 percent or what, but there would be some people that have that belief?

A Let me clarify. Anybody who thinks that there is some benefit in preservative-free, that would be inconsistent with the published literature and they would be operating on the basis of speculation and opinion that is not held by science.

Q So if someone didn't like triamcinolone for some reason or another, would you say that they don't know what they're talking about?

A No.

Q Doctors are entitled to their opinions. They all have training and things like that, right? So some doctors do believe differently than other doctors, right?

A Okay.

Q Do you not agree with that?

A No, that's fine. I said okay. But triamcinolone is a manufactured product. If they want to use betamethasone, that's a manufactured product.

opinions wouldn't change from then until now, right?

A Probably not. I don't know what I said.

Q Well, if the issue was debunked and was a non-issue in the late '90s, why would anyone need to come out in 2015 as a consensus and say it's not a problem?

A I can answer that question. Because physicians all around the country, like Dr. Bhambhani, were misguided and felt like, oh, I need to use preservative-free. That's why they came out. There were other physicians besides Dr. Bhambhani that were misguided.

Q So anyone that used preservative-free drugs because of a concern for arachnoiditis or some other irritation, they would be misguided?

A That's correct. From clinical a perspective, absolutely.

Q But, in fact, there are certain circumstances where you still can use preservative-free drugs, right?

A Well, the doctor would have to write a prescription specific to that patient, laying out the

foundation and why he was doing it and then he would have to go ahead and get it.

Here is one of the interesting ironies of this case: Those drugs that were benzyl alcohol-free were available from manufacturers. Upjohn made a product and so did Alcon. So the whole point here is Dr. Bhambhani was of the impression that having no benzyl alcohol was better for her patients, yet there were manufactured versions of injectable steroids that were benzyl alcohol-free. But she chose to go to a compounding pharmacist that couldn't possibly be anywhere near the equivalent standard of a legitimate manufacturer. Besides, it was against the law for her to do that anyway.

Q She and other health care providers in 23 states, right, just to be clear?

A Being ignorant of your responsibility as a physician and deviating from the standard of care, no matter how many you put on board, is still a deviation of the standard of care. These guys deviated from the standard of care.

Q Anyone who did that is unreasonable,

correct? Is that your position?

A No. I just laid out there is no basis for using it. The number one basis for using a compounding pharmacist is you have to have a reason. You have no reason. But on top of that, even if you thought you had a reason, manufacturers made a product without benzyl alcohol so there was no reason to ever consider to go to a compounding pharmacist.

Q No reasonably prudent physician would go to a compounding pharmacist for preservative-free MPA?

A Not at that time because there were products available in the United States manufactured to an appropriate standard that could be used.

Q But yet physicians in hospitals in 23 states did so, correct?

A You know, it's interesting. If you go to a flee market and you see some people getting some rip-off Rolex watches, lots of people are going over there and getting Rolex watches and they are happy with the Rolex watches and think they are great. They might be happy with the Rolex watches, but the probability of that Rolex that you are getting from the flee market

for 20 bucks is probably not going to be the same quality as getting a Rolex from a certified jeweler.

Q Dr. Bhambhani wasn't trying to buy a ripped off Rolex watch, was she?

A No, but Dr. Bhambhani was misguided and so were a number of other physicians that you are claiming here that did the same thing. It doesn't make a difference that there were a lot of them that did it. They were all misguided. They all made the mistake. Their decisions are not supported in science and there is no one in here who can come in here and say there is a scientific basis for that. In fact, David Main, who wrote an opinion on this case, didn't even touch that. That's the hot third rail. He wrote in his note, Dr. Bhambhani, she wished to use preservative-free. He did not even attempt to address the issue that, one, there was no basis for it and, number two, it's against the law.

Q Well, she provided the basis for why she used it, didn't she, in her deposition?

A It's irrelevant what her opinion is because it's not consistent with the practice of medicine and

what we know as doctors.

Q So Dr. Bhambhani, who also has a medical degree, she's well trained, she's been doing epidural steroid injections for however many years, but yet her opinion in terms of the care of her patients doesn't matter?

A Well, in this one particular niche, she is inadequately trained. Period.

Q It's not against the law to use preservative-free drugs, right?

A Yes, it is, in terms of the laws that regulate -- in this particular case, yes, because as a physician you are not allowed to use a compounded product if there is a commercially manufactured product available. So that is a deviation from acceptable medical practice to use a compounder if you actually have a product that's available.

Number two, you are never supposed to use a compounder as a manufacturer. You are only supposed to use a compounder when you have a specific reason to use it. So if you had a single patient who had special needs, by all means use the compounder, but you cannot

use a compounder to make all your methylprednisolone that you'll need that coming month.

Q You said that there were other products available. I know that you touched on it a little earlier, but I want to make sure I have them all down. What are all that you said? Upjohn had a product?

A Yes, Upjohn has a product.

Q Is that now Pfizer?

A It's Upjohn Pfizer.

Q So that's the Depo-Medrol?

A Yes. They are single-dose vials of Depo-Medrol and do not have benzyl alcohol.

Q You are saying there were no shortages of Depo-Medrol at that time?

A There were no shortages of -- there were shortages from time to time, but never at any time was there shortages of all the medication. So there was always one. No one has ever determined that one is better than the other. So if there wasn't enough Depo-Medrol, you could you triamcinolone, and if there was not enough triamcinolone, you could use betamethasone, all from certified manufacturers.

Q Right. So what you are saying is then the physicians don't have the choice? If they don't like triamcinolone or betamethasone and don't want to use it and there is a drug shortage, they have to use those other products anyway?

A Well, yeah. If the product they need for their patient is not available for whatever reason, then they can write an appropriate prescription to have for that patient a product made.

Q Anything else other than the Depo-Medrol from Pfizer?

A Well, there's Triesence, T-R-I-E-S-E-N-C-E.

Q Who makes that?

A Alcon.

Q And that is preservative-free?

A Yes. That's triamcinolone.

Q What other MPA was there available?

A This is triamcinolone, depo steroids.

Q When you said there was other product available, what I'm talking about --

A For benzyl alcohol-free products, you had the triamcinolone product and you had the Pfizer

product.

Q Is there any other MPA version of the product?

A That's the only one, the Pfizer Upjohn.

Q And as you sit here today, you can't say whether there was a shortage or not at that time?

A I don't believe there was.

Q What evidence do you have that there wasn't a shortage?

A I can't present any evidence, but I don't believe there was at that time.

Q And what's the basis for that?

A I think the only shortage was back in 2007, but I would have to go research that. My point was not at any given time were all three of the major depo steroids not available.

Q I want to show you a couple of things. Do you agree that NECC held themselves out to the community and its customers as being a reliable organization?

MR. COREN: Objection as to the form.

A I can only talk about my personal experience

A No.

Q But you would agree that the conclusion drawn was that Brigham and Women's was -- hold on. Let me find it. That they were approved for sterile compounding preparations for Brigham and Women's Hospital?

MR. COREN: Objection to form.

A I would have to look at the actual sentence, but I do know that Brigham and Women's did continue to do business with NECC.

BY MR. KIRBY:

Q So you are kind of drawing the conclusion?

A Yes.

Q For the record, that's Exhibit 302.

When we talked earlier, you don't think that Dr. Bhambhani needed -- or anybody for that matter had to go and inspect NECC themselves, right?

MR. COREN: Objection as to form.

BY MR. KIRBY:

Q Before using them?

A No.

Q Let me cut to the chase. Is there any

amount of due diligence that Dr. Bhambhani or other health care providers could have done in your mind to make NECC a supplier of preservative-free MPA?

MR. COREN: Objection to form.

A Yes. The first order of business is they have to establish whether there is a need for having it. So if she would have done due diligence, she would have found there was no need and therefore would have quickly saved her patients' complications by never using NECC. So that's -- and we know she did no due diligence because she admitted it in her deposition.

BY MR. KIRBY:

Q But you can't say if she had done due diligence whether she would have found there was a drug shortage or not?

MR. COREN: Objection to the form.

A She would have found that to need a compounding pharmacy, you have to have a special need that's specific enough to write a prescription specific.

BY MR. KIRBY:

Q You said I think before that if there was a

need, meaning there wasn't a commercially -- well, two things: That if there wasn't a commercially available product of methylprednisolone acetate preservative-free, then she could get it from a compounding pharmacy, right?

A No. There were other products that were equally as good that would substitute. Nobody has ever demonstrated any improvement of Depo-Medrol or methylprednisolone over the triamcinolone and betamethasone. And as I mentioned earlier, there is data accruing now that Depo-Medrol may have more of a hazard in terms of a gluten issue and emboli.

Q And that's your opinion?

A No. That's been published.

Q But you are not foreclosing that other reasonably prudent and trained physicians might have a different opinion?

A About what?

Q That methylprednisolone acetate is better or that there is a reason not to use triamcinolone or betamethasone.

A Nobody has that opinion -- well, I don't

want to do absolute certainty. There is no scientific literature published that supports that there is benefit of one product over another. Period. There are publications now that suggest that there is increased risk in terms of emboli when you get into a blood vessel with Depo-Medrol over the other smaller particles.

Q So are there different lengths of therapeutic effect when you compare triamcinolone, betamethasone and methylprednisolone?

A Generally not. There are a lot of variables to look at here. For depo steroids, they can have their antiinflammatory effect in situ for maybe four to six weeks. They all seem to be about the same. But when you look at a cross-section of the population who has gotten epidural steroids, whatever variety of depo steroids, they all seem to do about the same. Nobody has ever specifically found depo or triamcinolone or betamethasone better than one of the other.

Q So triamcinolone is particle free?

A No. It's smaller particles. The largest particles are Depo-Medrol, then triamcinolone is much

A I do not.

Q You do not. Okay.

So other than finding out whether she was allowed to use a compounder I guess, is there anything else that you are saying that Dr. Bhambhani needed to do as some sort of due diligence?

A So she would have found out that compounders are only supposed to be used when you have a reason and then she would have found out if she did due diligence that the only way you can communicate to a compounder is that you have to write a patient-specific prescription for that patient's need and it has to be written specific.

Q So other than those two things, and we'll touch on those two things, you are not saying that she needed to submit a FOIA request or public information request to the FDA or anything, are you?

A No. She's a physician. She's expected to operate along the standard of care of all physicians. And the use of a compounding pharmacist is something that we've all used in our practices and there are set rules of engagement on how to use a compounding

pharmacy. We call them the standard of practice, and she violated the standard of practice.

Q You said she's required to follow the standard of practice that all physicians use, right? You meant reasonably prudent physicians, correct? You are not saying that every physician always has the same standard of practice?

A No, they all have the same. This is the law. This is the law that operates in the United States. She and all other physicians are required to do this. And if they don't do it, even if there are 100 of them, they are all wrong. The law stipulates what you have to do. It's in the Cosmetic Act of 1938 and it's followed up with the 1992 revision.

Q So you are saying that Dr. Bhambhani broke the law?

A Yes.

Q Can you give me any example of any physicians across the country who ordered the same way that Dr. Bhambhani did who were ever prosecuted or charged or reprimanded or anything for ordering the

drugs the way they did?

A It's a deviation from the standard of care. Doctors don't have those kinds of charges. They get malpractice cases like we are here.

Q You had made the distinction that it was a law and she broke the law. That is why I followed up with that.

So you can't tell me that anyone was actually reprimanded or charged or anything with regards to the way they ordered the drugs from NECC?

A No -- well, that's not true. The way that's handled at the physician level is through civil litigation and a lawsuit like this. She is now getting reprimanded through this litigation.

Q But you are talking -- you tell me. What laws are you talking about? What laws did she break?

A She violated the Federal Food, Drug and Cosmetic Act of 1938.

Q Anything else?

A That's it. That's the main act. And then they modified it in 1992. So obviously the law requires that there be a prescription specific to the

A Yes.

Q Let's assume she bought the MPA from an FDA registered manufacturer. You can't foreclose the idea that that FDA manufacturer isn't experiencing some sort of contamination event or other adverse production issue, can you?

A No, but -- well, we have a history of 50 years that they have had no infections and we also have a history of multiple different callbacks for various violations let's say in the protocols. But none of those actually amounted to being an infection. So the industry, the manufacturing industry, has a hairpin trigger. They are constantly doing callbacks because they are looking at small violations and calling back product just to be safe. We don't have that with compounders. It just goes out and they do end-product testing.

Q I understand your answer, but my simple question is that just because she orders from an FDA registered manufacturer doesn't mean that there is no chance that there could be a problem.

MR. COREN: Objection as to the form.

BY MR. KIRBY:

Q I understand the caveat that you added, but my premise is also correct, right?

A Nothing rules out 100 percent. But in terms of the probability of having a problem, you are more likely to have a problem with a compounding pharmacist because they don't achieve the same standards as manufacturers. But is it absolute zero? No, it's never zero. But the probability of having a problem is higher with compounding and hence we have a dozen outbreaks for compounders and zero for manufacturers.

Q But again we can't say how much higher or how many people were injured with the compounding drugs than the --

A Oh, yeah, I can do that. Zero for manufacturers. So if you were to work out the numbers, those numbers alone, since we're using zero, compounders are infinitely more dangerous and have a higher risk, infinite, because manufacturers have zero.

Q So what were all the injuries in these 12 outbreaks using compounding pharmacy drugs? What was the injury sustained?

Q Did you also have an opinion with regard to informed consent?

A Yes.

Q What's your opinion with regard to informed consent?

A Informed consent is only appropriate and considered informed consent when the physician complies with the standard of care. Informed consent, a patient just assumes their doctor is going to do everything to the appropriate standard of care and in the event that something happens, they have an understanding that things happen when you stick to the standard of care. In this particular case, Dr. Bhambhani deviated from the standard of care at multiple different levels and the patients were not aware of that. The patients did not know that she was providing them with a compounded substance when they had access to a manufactured substance that was essentially with less risk, maybe even no risk, in terms of infection compared to the compounded substance.

Q What exactly was Dr. Bhambhani required to tell her patients to be in accordance with the standard

of care as to obtaining informed consent?

MR. COREN: Objection as to the form.

A Well, if you are going to be using a non FDA certified product over an available product, you need to tell them why.

BY MR. KIRBY:

Q And that would be true if it was dye as well? It's not just steroids, right?

A If you are using a product that is compounded and there is an FDA manufactured product that's exactly the same, you better tell them because that would be a deviation from acceptable medical practice. You only can use compounded products if there is a reason for it and if there is not an FDA manufactured product that suits your needs.

Q So anytime you use a compounded drug, if there is an FDA registered manufactured product available, you have to tell them about that? I'm not questioning you. I'm just asking you to confirm.

A Well, the answer is sort of yes. If there is a manufactured product, you use that product. That's the standard of care. If you don't use that

product, you are deviating from the standard of care. There is no place on earth that says the standard of care is to use a compounded substance when you have an equivalent substance that comes from a manufacturer. Nobody can say that the standard of care says it's okay to use compounded substances when there is a manufactured FDA approved substance.

Q I'm just focussing on informed consent and what Dr. Bhambhani had to say to her patients.

A She needed to tell them that she was going outside the protective system for patients. She was no longer working inside the protections that the FDA provided. She was working outside the system. And at this point, it's her decision making. There is no FDA to help her.

Q Do they then have to explain the FDA regulatory process and how that works and how the product obtains FDA approval and how it was tested and things like that?

A Well, Dr. Bhambhani doesn't know the difference between --

Q Well, that wasn't my question, if you are